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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,212	11/16/2001	Preeti Lal	PF-0221-3 DIV	9736

22428 7590 04/18/2005

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/991,212	LAL ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7,9,10,12-16,28,29,46-48 and 57-59* is/are pending in the application.

4a) Of the above claim(s) *14-16,28,29,47 and 59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7,9,10,12,13,46,48,57 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. 3/23/05
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] At the examiner's request this application has been returned to the examiner for further consideration after being forwarded to the Board of Patent Appeals and Interferences.

[2] PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

[3] Claims 3-7, 9-10, 12-16, 28-29, 46-48, and 57-59 are pending in the application.

[4] Claims 14-16, 28-29, 47, and 59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/2/2002.

[5] Claims 3-7, 9-10, 12-13, 46, 48, and 57-58 are being examined on the merits.

[6] Appellants' arguments filed 12/29/2003 have been fully considered.

[7] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[8] Claim(s) 3, 6-9, 12-13, 46, 48, and 57-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

[a] The term "naturally-occurring" in claims 3 (claims 6-9 dependent therefrom), 12 (claim(s) 48 dependent therefrom), 13 (claim(s) 46 dependent therefrom), and 57-58 is indefinite as it is unclear as to how a skilled artisan distinguishes a "naturally-occurring" sequence from a non-naturally-occurring sequence. In other words, what characteristics or features distinguish a sequence that is "naturally-occurring" from those sequences that are not naturally occurring? In the absence of such characteristics or features, it is unclear as to the scope of claimed polynucleotides. It is suggested that applicants clarify the meaning of the term "naturally-occurring."

[b] The term "transports phosphate" in claim 3 (claims 6-9 dependent therefrom) is indefinite as it is unclear as to the meaning of the term. The term can be interpreted as meaning a fragment of SEQ ID NO:1 that is phosphorylated and wherein the fragment is transported intracellularly or intercellularly or, alternatively, the term can be interpreted

as meaning a fragment of SEQ ID NO:1 that has phosphate transporter activity. It is suggested that applicants clarify the meaning of the term.

Claim Rejections - 35 USC § 101

[9] The rejection of claims 3-7, 9-10, 12-13, 46, 48, and 57-58 under 35 U.S.C. 101 and the corresponding enablement rejection of claims 3-7, 9-10, 12-13, 46, 48, and 57-58 under 35 U.S.C. 112, first paragraph, are maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: At p. 2 of the response filed 12/29/2003 (II.A), applicants argue the examiner does not disprove SEQ ID NO:2 is expressed in humans and all or most human expressed polynucleotides have specific and substantial utility.

There is no dispute that the preponderance of evidence suggests that SEQ ID NO:2 is expressed in humans. However, the examiner clearly disputes appellants' assertion that all human expressed polynucleotides have a specific and substantial utility for "measuring undesired side effects of drug candidates" at least for the reasons of record, particularly for the reasons that further experimentation is required to use SEQ ID NO:2 for the asserted uses.

At the top of p. 3 of the response (II.A), applicants argue the examiner insists that applicants prove reasonable probability of utility and function of the claimed invention. Applicants argue nothing in the law requires proof of biological function. Applicants argue the function of SEQ ID NO:2 is irrelevant. Applicants argue that because human expressed polynucleotides are "predominantly" useful, the claimed invention is useful.

Appellants' argument is not persuasive. The examiner has never required proof of function. However, the function of the polypeptide encoded by SEQ ID NO:2 is relevant to the extent an asserted utility for SEQ ID NO:2 is the production of SEQ ID NO:1. The examiner disagrees with appellants' assertion that the claimed invention is useful for the reasons of record.

At the top of p. 4 of the response (II.B, item 1), appellants again argue that the function of SEQ ID NO:1 is irrelevant. Although appellants assert the function of SEQ ID NO:1 is irrelevant, appellants go on to argue that SEQ ID NO:1 is a member of the phosphate transporter family of proteins and how a skilled artisan would conclude that "the claimed polynucleotides would more likely than not have utilities based on the phosphate transport function of the encoded polypeptides."

Appellants' argument is not found persuasive. As noted above, there is no requirement that applicant demonstrate biological activity of a polynucleotide for patentable utility – only that the polynucleotide has a specific and substantial asserted utility. To the extent applicants continue to argue that SEQ ID NO:2 encodes a polypeptide that has phosphate transport activity, the examiner maintains that function can only be determined empirically by, e.g., activity assay or identification of key amino acids that impart biological activity. In this case, it is just as likely that the encoded polypeptide is non-functional. For the reasons of record, the claimed invention has no patentable utility, regardless of whether the encoded polypeptide has phosphate transport function.

Also, it is noted that a polypeptide, NPT4, is disclosed by Ruddy et al. (Genome Res 7:441-456, see particularly p. 450, Figure 6B) that is nearly identical to the polypeptide encoded by SEQ ID NO:1. It is noted that Ruddy et al. properly identify NPT4 as a "predicted" sodium phosphate transporter protein. Further, Ruddy et al. disclose "[w]hat role either of these two newly discovered genes may play in these particular hypophosphatemias is awaiting determination" (p. 453, middle). Thus, Ruddy et al. recognize that further experimentation is required to determine the biological significance of the NPT4 gene.

At the top of p. 5 of the response (II.B, item 2), appellants argue that they need not demonstrate whether SEQ ID NO:2 is differentially expressed in normal and diseased tissues. Applicants argue SEQ ID NO:2 is useful in toxicology testing regardless of differential expression.

Appellants' argument is not found persuasive. The examiner's statements addressed an asserted utility of using SEQ ID NO:2 as a diagnostic for disease, not necessarily for the use of SEQ ID NO:2 in toxicology testing. The examiner agrees that a demonstration of differential expression of SEQ ID NO:2 is not *required* for patentable utility. However, regarding the use of SEQ ID NO:2 in toxicology testing, it is the examiner's position that further experimentation is required to interpret the results of such testing.

At the middle of p. 5 of the response (II.B, item 3), appellants argue that Incyte's customers subscribe to their database to purchase polynucleotides described in the

database. Appellants argue the examiner refuses to accept this evidence of commercial success of the claimed invention.

Appellants' arguments are not persuasive. There is no evidence of record that Incyte's customers subscribe to their database for purchase of SEQ ID NO:2, i.e., there is no evidence that SEQ ID NO:2 enjoys such commercial success.

At the bottom of p. 5 of the response, (II.B, item 4), appellants dispute the examiner's position that the use of SEQ ID NO:2 for gene and protein expression monitoring are not specific. Appellants argue the examiner substitutes his own judgment for the judgment of Appellant's alleged expert. Appellants argue that the Bedilion declaration demonstrates how a skilled artisan would have understood the specification to disclose the use of SEQ ID NO:2 for gene expression monitoring.

Appellants' argument is not persuasive. For the reasons of record, the examiner maintains the position that any nucleic acid – including SEQ ID NO:2 – can be used for gene expression monitoring.

At the top of p. 6 of the response, (II.B, item 5), appellants argue SEQ ID NO:2 can be used for toxicology testing regardless of whether SEQ ID NO:1 is a drug target. Appellants argue the claimed polynucleotide is useful for toxicology testing of potential drugs targeted to other polynucleotides/polypeptides.

Appellants' argument is not persuasive. For reasons of record, the use of SEQ ID NO:2 in toxicology testing is not specific (as noted above) and is not substantial as further experimentation is required to interpret the results of such testing.

At the bottom of p. 6 of the response (II.B, item 6), appellants dispute the examiner's position regarding the use of SEQ ID NO:2 as a control in toxicology testing. Appellants argue that if all polynucleotides can be used as such controls, then they all have that utility. Appellants argue that nothing in the law states that an invention must have a unique utility. Appellants argue the examiner is factually incorrect in stating that any polynucleotide could be used for such a control as "a random, non-naturally occurring sequence would most likely not be useful as a control for toxicology testing."

Appellants' argument is not persuasive. In this case, appellants' argument supports the examiner's position that the use of SEQ ID NO:2 in gene expression analysis is not specific as appellants' argument appears to be that any nucleic acid can be used for toxicology testing. While appellants' characterize the examiner's position as being "factually incorrect," it is noted that any nucleic acid can be used for gene expression analysis, including random and non-random sequences, just as any nucleic acid can be used as a molecular weight marker or for protein expression. While some nucleic acids will be more useful than others, all nucleic acids have such uses. It would appear that appellants are arguing the degree to which a utility is non-specific. However, a non-specific utility is a non-specific utility, regardless of degree. The examiner is, in fact, correct in asserting that any nucleic acid *can* be used as a probe. Appellants are invited to provide evidence that any nucleic acid cannot be used for a probe in gene expression analysis.

At the top of p. 7 of the response (II.B, item 7), appellants argue that only some of the utilities discussed in the Bedilion declaration require knowledge of function.

Appellants argue that the use of SEQ ID NO:2 as a control in toxicology testing is not one of them.

Appellants' argument is not persuasive. Even assuming arguendo the function of SEQ ID NO:1 is not required to use SEQ ID NO:2 as a control in toxicology testing, as noted above, in accordance with appellants' position, any nucleic acid can be used as a control. Consequently, the asserted utility is not specific.

At the middle of p. 7 of the response (II.B, item 8), appellants argue the examiner "refuses to consider that the claimed polynucleotide is a research tool" to "study drug candidates targeted to **other** polynucleotides in toxicology tests" (emphasis in original).

Appellants' argument is not persuasive. The examiner maintains that the specification fails to provide the necessary guidance for interpreting the results obtained from the use of SEQ ID NO:2 in gene expression monitoring for toxicology testing for the reasons already made of record.

At the bottom of p. 7 of the response (II.B, item 9), appellants argue the claimed polynucleotide is useful for measuring the toxicity of drug candidates targeted to polynucleotides and polypeptides other than the claimed nucleic acid. Appellants argue this utility is specific to the polynucleotide used in the toxicology test.

Appellants' argument is not persuasive. As noted above, appellants admit that any nucleic acid can be used for toxicology testing and consequently, this asserted use for the claimed nucleic acid is not specific. Further, the examiner maintains that the

specification fails to provide guidance for interpreting any result(s) obtained from such testing.

At the top of p. 8 of the response (II.B, item 10), appellants argue that if expression of a particular polynucleotide is affected in any way by exposure to a test compound and if that polynucleotide is not the specific target of the test compound, this is an indication that the test compound has undesirable toxic side effects. Appellants argue such an indication is specific for every individual polynucleotide sequence.

Appellants' argument is not persuasive. The examiner maintains that there is no evidence of record that – at the time of the invention – one would have had the ability to interpret the results of gene expression monitoring using the claimed polynucleotide.

At the bottom of p. 8 of the response (II.B, item 11), appellants argue SEQ ID NO:1 could "reasonably" belong to the phosphate transporter class of polypeptides based on structural homology to a known member of this class. According to appellants, all members of this class are useful and it follows that SEQ ID NO:1 is useful.

Appellants' argument is not persuasive. Although appellants argue that the biological function of SEQ ID NO:1 is irrelevant, appellants nonetheless continue to argue that SEQ ID NO:1 has the function of a phosphate transporter. It is noted that it is just as reasonable that SEQ ID NO:1 is a non-functional mutant polypeptide. Moreover, even assuming arguendo SEQ ID NO:1 has phosphate transporter activity, the examiner knows of no specific and substantial or well-established use for all phosphate transporters. In other words, just because a polypeptide has the ability to transfer

phosphate across a biological membrane, this is no indication that the polypeptide has a "real world" use.

Appellants summarize their arguments at p. 9 (II.C). As the examiner believes that all arguments have been addressed above, no response to the summary is necessary.

At least for the reasons of record and the reasons stated above, the asserted utilities for the claimed polynucleotide/array are neither specific nor substantial.

Claim Rejections - 35 USC § 112, First Paragraph

[10] Claims 13, 46, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description".

In the amendment filed 12/23/2002, applicants amended claims 13 (claim(s) 46 dependent therefrom) and 58 to recite the limitation "nucleotides 1183 through 1454 of...SEQ ID NO:2." In the corresponding remarks, applicants assert "[t]he portion of

SEQ ID NO:2 consisting of nucleotides 1183 through 1454 corresponds to the polynucleotide disclosed as Incyte Clone 754412.est at, for example, page 38, lines 11-12 and 24-25, and shown as SEQ ID NO:5 in the Sequence Listing" (p. 36, middle). The examiner has carefully reviewed appellants' asserted support for amended claims 13 and 58. It appears that applicants rely on the sequence of SEQ ID NO:5 as support for the recited limitation as there does not appear to be explicit support for the recited range of nucleotides in the specification, claims, and drawings as originally filed. However, the sequence of SEQ ID NO:5 fails to support such a range of nucleotides as SEQ ID NO:5 is not a subsequence of SEQ ID NO:2 as evidenced by the sequence alignment at pp. 52-53 of the Office action mailed 3/21/2003. As the examiner can find no support for the recited limitation, the claims fail to meet the written description requirement of 35 U.S.C. 112, first paragraph.

[11] The written description rejection of claims 3, 6-7, 9, 12-13, 46, 48, and 57-58 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: At the bottom of p. 9 of the response (III.A), appellants argue the examiner fails to provide evidence that a skilled artisan would have not have recognized that appellants were not in possession of the genus of claimed polynucleotide variants and fragments. Appellants argue the examiner's position is contrary to the written description Guidelines. Appellants argue the claimed variants are defined in terms of SEQ ID NO:1 and 2 and the examiner's position is "nothing more

than a misguided attempt to require Appellants to unduly limit the scope of their claimed invention."

Appellants' argument is not persuasive. At least for reasons already made of record, the genus of claimed variants and fragments is not described in accordance with the requirements of 35 U.S.C. 112, first paragraph.

At the bottom of p. 10 of the response (III.B, item 1), appellants argue that the examiner is incorrect in asserting that a textual description would not allow a skilled artisan to visualize the structures of members of the genus.

Appellants' argument is not persuasive. At least for reasons already made of record, the genus of claimed variants and fragments is not described in accordance with the requirements of 35 U.S.C. 112, first paragraph.

At the middle of p. 11 of the response (III.B, item 2), appellants argue that it is not necessary that every member of the genus of claimed variants and fragments have the alleged phosphate transporter activity in order for the claimed nucleic acid to meet the written description requirement.

Appellants' argument is not persuasive. At least for reasons already made of record, the genus of claimed variants and fragments is not described in accordance with the requirements of 35 U.S.C. 112, first paragraph.

At the top of p. 12 of the response (III.B, item 3), appellants argue the claimed polynucleotide has been described by structural, chemical, and physical features sufficient to satisfy the written description requirement.

Appellants' argument is not persuasive. At least for reasons already made of record, the genus of claimed variants and fragments is not described in accordance with the requirements of 35 U.S.C. 112, first paragraph.

At the bottom of p. 12 of the response (III.B, item 4), appellants rely on the Brenner reference as providing evidence that the claimed genus of variants has a "low degree of variation."

Appellants' argument is not persuasive. At least for reasons already made of record, the genus of claimed variants and fragments is not described in accordance with the requirements of 35 U.S.C. 112, first paragraph.

At the top of p. 13 of the response (III.B, item 5), appellants argue it is not necessary to divine the function of all members of the genus because the description of the claimed nucleic acids satisfies the written description requirement of 35 U.S.C. 112, first paragraph.

Appellants' argument is not persuasive. At least for reasons already made of record, the genus of claimed variants and fragments is not described in accordance with the requirements of 35 U.S.C. 112, first paragraph.

Appellants summarize their arguments at p. 13 (III.C). As the examiner believes that all arguments have been addressed above, no response to the summary is necessary.

[12] Even if appellants demonstrate the polynucleotide encoding SEQ ID NO:1 has a specific and substantial or well-established utility, the scope of enablement rejection of

claims 3, 6, 7, 9, 12, 13, 46, 48, 57, and 58 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below.

RESPONSE TO ARGUMENT: At the top of p. 14 of the response (IV), appellants argue a skilled artisan would know how to make and use the claimed polynucleotides. Appellants argue that even those polynucleotides that have biological activity other than encoding polypeptides having phosphate transport activity are useful as hybridization probes. Appellants argue the examiner fails to indicate how or why the recited fragments/variants could not be used as hybridization probes.

Appellants' argument is not persuasive. At least for reasons already made of record it is the examiner's position that undue experimentation is required to make and use the full scope of claimed variants and fragments. In response to appellants argument regarding hybridization probes, the examiner acknowledges that some of the polynucleotides encompassed by the scope of the claims can be used for detection of SEQ ID NO:2. However, a vast number will not be so useful due to variation within their sequences. Further, even assuming arguendo SEQ ID NO:2 was found to be useful in gene expression monitoring, there is no evidence of record that degenerate variants of SEQ ID NO:2 are so useful as there is no evidence of record that such degenerate variants are expressed.

At the middle of p. 15 of the response (IV), appellants argue one of skill in the art would know how to make and use polynucleotides "comprising" the recited fragments and variants, without an explicit disclosure of all possible elements that could be a part of – but are not essential to – the claimed invention.

Appellants' argument is not persuasive. At least for reasons already made of record it is the examiner's position that undue experimentation is required to make and use the full scope of claimed variants and fragments.

At the middle of p. 16 of the response (IV), appellants argue that one of skill in the art would know how to use the full scope of claimed polynucleotides as controls in toxicology testing.

Appellants' argument is not persuasive. At least for reasons already made of record it is the examiner's position that the asserted utility for the claimed polynucleotide is neither specific nor substantial and further that undue experimentation is required to make and use the full scope of claimed variants and fragments.

At the bottom of p. 16 of the response (IV), appellants argue that one of skill in the art would reasonably conclude that SEQ ID NO:1 has phosphate transport activity, relying on Brenner to support their conclusion. Appellants argue the examiner has provided no evidence to support a high level of unpredictability of functional annotation. Appellants attempt to disregard the teachings of the references cited by the examiner as supporting the high level of unpredictability in altering a protein's sequence with an expectation of maintaining a desired activity/utility. Appellants reiterate their argument that polynucleotides that are structurally related to SEQ ID NO:2 – regardless of their function – can be used as hybridization probes.

Appellants' argument is not persuasive. At least for reasons already made of record and those stated above, it is the examiner's position that undue experimentation is required to make and use the full scope of claimed variants and fragments.

Claim Rejections – Double Patenting

[13] The obviousness-type double patenting rejection of claims 3-7, 9-10, 12, and 57 as being unpatentable over claims 1-8 of US Patent 5,985,604 is maintained for the reasons of record. The examiner acknowledges appellants' request that the requirement for submission of a Terminal Disclaimer be held in abeyance.

[14] Claim 12 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 12 of copending Application No. 10/877,818. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

[15] Claims 3-7, 9-10, 13, 46, 48, and 57-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-7, 9-10, 12, 48-55, and 57 of US non-provisional application 10/877,818 ('818 application). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 3-7, 9-10, 13, 46, 48, and 57-58 of the instant application are generic to all that is recited in claims 3-7, 9-10, 12, 48-55, and 57 of the

'818 application. In other words, claims 3-7, 9-10, 13, 46, 48, and 57-58 of the instant application are anticipated by claims 3-7, 9-10, 12, 48-55, and 57 of the '818 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

[16] Claim(s) 3, 6-7, 9, 12-13, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Feder et al. (US Patent 5,872,237; cited in the IDS filed 11/16/2001). Claim 3 is drawn to (in relevant part) a nucleic acid encoding: 1) a polypeptide that is at least 90% identical to SEQ ID NO:1 or 2) a fragment of a polypeptide of SEQ ID NO:1 that transports phosphate. Claim 6 is drawn to a recombinant polynucleotide comprising a promoter sequence operably linked to the nucleic acid of claim 3. Claim 7 is drawn to a host cell transformed with the recombinant polynucleotide. Claim 9 is drawn to a method of producing a polypeptide encoded by the nucleic acid of claim 3. Claim 12 is

drawn to (in relevant part) a nucleic acid comprising a sequence that is at least 90% identical to SEQ ID NO:2, a complement thereof, and an RNA equivalent thereof. Claims 13 and 58 are drawn to (in relevant part) a nucleic acid comprising at least 20 or 60 nucleotides of nucleotides 1183-1454 of SEQ ID NO:2, a sequence at least 90% identical thereto, complements thereof, and RNA equivalents thereof.

The reference of Feder et al. discloses an isolated nucleic acid, SEQ ID NO:19, that is 90.7% identical to SEQ ID NO:2 and encodes a polypeptide that is 99.3% identical to SEQ ID NO:1 (see Appendices A and B). Feder et al. teaches the nucleic acid can be RNA or DNA (column 8, bottom). Feder et al. teaches the nucleic acid encodes a sodium-phosphate transporter polypeptide (columns 24-26) and teaches methods of producing a polypeptide using a host cell transformed with an expression vector comprising the nucleic acid (columns 10-13).

This anticipates claims 3, 6-7, 9, 12-13, and 58 as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[17] This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

[18] Claims 46 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feder et al. in view of Schena et al. (Science 270:467-470; cited by applicants in the Declaration filed 8/15/2003). Claim 46 is drawn to a microarray comprising the polynucleotide of claim 13. Claim 48 is drawn to an array comprising a polynucleotide, including an oligonucleotide, that is complementary to at least 30 nucleotides of a polynucleotide of claim 12.

The reference of Feder et al. discloses the teachings as described above. The reference further teaches methods for measuring DNA or RNA by hybridization (columns 13-14 and 21) and teaches an analysis of gene expression of a plurality of nucleic acids, including SEQ ID NO:19 of Feder et al., by Northern blotting (column 26). Feder et al. do not teach measuring expression of the nucleic acid using a microarray or an array.

The reference of Schena et al. teaches the use of a cDNA microarray for simultaneous gene expression monitoring of a plurality of cDNAs.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to make and use a cDNA microarray comprising the nucleic acid of Feder et al.

to measure gene expression in various human tissues. One would have been motivated to make a cDNA microarray comprising the nucleic acid of Feder et al. in order to measure gene expression in various human tissues simultaneously rather than measuring the expression of each nucleic acid individually by Northern blotting. One would have a reasonable expectation of success for making a cDNA microarray comprising the nucleic acid of Feder et al. because of the results of Feder et al. and Schena et al. Therefore, claims 46 and 48, drawn to a microarray or an array as described above would have been obvious to one of ordinary skill in the art.

Conclusion

[19] Status of the claims:

Claims 3-7, 9-10, 12-13, 46, 48, and 57-58 are pending.

Claims 3-7, 9-10, 12-13, 46, 48, and 57-58 are rejected.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Thursday and alternate Fridays from 6:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

04-12-05

DAVID J. STEADMAN, PH.D.
PRIMARY EXAMINER

APPENDIX A

```
RESULT 5
AR036571
LOCUS       AR036571               1780 bp    DNA     linear   PAT 29-SEP-1999
DEFINITION  Sequence 19 from patent US 5872237.
ACCESSION   AR036571
VERSION     AR036571.1  GI:5953239
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 1780)
  AUTHORS   Feder,J.Nathan., Kronmal,G.Scott., Lauer,P.M., Ruddy,D.A.,
            Thomas,W., Tsuchihashi,Z. and Wolff,R.K.
  TITLE     Megabase transcript map: novel sequences and antibodies thereto
  JOURNAL   Patent: US 5872237-A 19 16-FEB-1999;
FEATURES             Location/Qualifiers
     source          1. .1780
                     /organism="unknown"
                     /mol_type="unassigned DNA"
ORIGIN

Alignment Scores:
Pred. No.:              3.78e-161      Length:         1780
Score:                  2061.00        Matches:        398
Percent Similarity:     99.50%         Conservative:   1
Best Local Similarity:  99.25%         Mismatches:     2
Query Match:            99.28%         Indels:         0
DB:                     6              Gaps:           0

US-09-991-212A-1 (1-401) x AR036571 (1-1780)

Qy          1 MetGlnValAspGluThrLeuIleProArgLysValProSerLeuCysSerAlaArgTyr 20
              ||||||||||||||||||||||||||||||||   ||||||||||||||||||||||||
Db        377 ATGCAAGTGGATGAGACACTGATCCCCAGGAAAGGTCCAAGTTTATGTTCTGCTCGCTAT 436

Qy         21 GlyIleAlaLeuValLeuHisPheCysAsnPheThrThrIleAlaGlnAsnValIleMet 40
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        437 GGAATAGCCCTCGTCTTACATTTCTGCAATTTCACAACGATAGCACAAAATGTCATCATG 496

Qy         41 AsnIleThrMetValAlaMetValAsnSerThrSerProGlnSerGlnLeuAsnAspSer 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        497 AACATCACCATGGTAGCCATGGTCAACAGCACAAGCCCTCAATCCCAGCTCAATGATTCC 556

Qy         61 SerGluValLeuProValAspSerPheGlyGlyLeuSerLysAlaProLysSerLeuPro 80
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        557 TCTGAGGTGCTGCCTGTTGACTCATTTGGTGGCCTAAGTAAAGCCCCAAAGAGTCTTCCT 616

Qy         81 AlaLysSerSerIleLeuGlyGlyGlnPheAlaIleTrpGluArgTrpGlyProProGln 100
              ||||||||||||||||||||||||||||||||||||||:::|||||||||||||||||
Db        617 GCAAAGTCCTCAATACTTGGGGGTCAGTTTGCAATTTGGGAAAAGTGGGGCCCTCCACAA 676

Qy        101 GluArgSerArgLeuCysSerIleAlaLeuSerGlyMetLeuLeuGlyCysPheThrAla 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        677 GAACGAAGCAGACTCTGCAGCATTGCTTTATCAGGAATGTTACTGGGATGCTTTACTGCC 736

Qy        121 IleLeuIleGlyGlyPheIleSerGluThrLeuGlyTrpProPheValPheTyrIlePhe 140
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        737 ATCCTCATAGGTGGCTTCATTAGTGAAACCCTTGGGTGGCCCTTTGTCTTCTATATCTTT 796

Qy        141 GlyGlyValGlyCysValCysCysLeuLeuTrpPheValValIleTyrAspAspProVal 160
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        797 GGAGGTGTTGGCTGTGTCTGCTGCCTTCTCTGGTTTGTTGTGATTTATGATGACCCCTTT 856

Qy        161 SerTyrProTrpIleSerThrSerGluLysGluTyrIleIleSerSerLeuLysGlnGln 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        857 TCCTATCCATGGATAAGCACCTCAGAAAAAGAATACATCATATCCTCCTTGAAACAACAG 916
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Qy       181 ValGlySerSerLysGlnProLeuProIleLysAlaMetLeuArgSerLeuProIleTrp 200
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       917 GTCGGGTCTTCTAAGCAGCCTCTTCCCATCAAAGCTATGCTCAGATCTCTACCCATTTGG 976

Qy       201 SerIleCysLeuGlyCysPheSerHisGlnTrpLeuValSerThrMetValValTyrIle 220
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       977 TCCATATGTTTAGGCTGTTTCAGCCATCAATGGTTAGTTAGCACAATGGTTGTATACATA 1036

Qy       221 ProThrTyrIleSerSerValTyrHisValAsnIleArgAspAsnGlyLeuLeuSerAla 240
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1037 CCAACTTACATCAGCTCTGTGTACCATGTTAACATCAGAGACAATGGACTTCTATCTGCC 1096

Qy       241 LeuProPheIleValAlaTrpValIleGlyMetValGlyGlyTyrLeuAlaAspPheLeu 260
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1097 CTTCCTTTTATTGTTGCCTGGGTCATAGGCATGGTGGGAGGCTATCTGGCAGATTTCCTT 1156

Qy       261 LeuThrLysLysPheArgLeuIleThrValArgLysIleAlaThrIleLeuGlySerLeu 280
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1157 CTAACCAAAAAGTTTAGACTCATCACTGTGAGGAAAATTGCCACAATTTTAGGAAGTCTC 1216

Qy       281 ProSerSerAlaLeuIleValSerLeuProTyrLeuAsnSerGlyTyrIleThrAlaThr 300
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1217 CCCTCTTCAGCACTCATTGTGTCTCTGCCTTACCTCAATTCCGGCTATATCACAGCAACT 1276

Qy       301 AlaLeuLeuThrLeuSerCysGlyLeuSerThrLeuCysGlnSerGlyIleTyrIleAsn 320
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1277 GCCTTGCTGACGCTCTCTTGCGGATTAAGCACATTGTGTCAGTCAGGGATTTATATCAAT 1336

Qy       321 ValLeuAspIleAlaProArgTyrSerSerPheLeuMetGlyAlaSerArgGlyPheSer 340
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1337 GTCTTAGATATTGCTCCAAGGTATTCCAGTTTTCTCATGGGAGCATCAAGAGGATTTTCG 1396

Qy       341 SerIleAlaProValIleValProThrValSerGlyPheLeuLeuSerGlnAspProGlu 360
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1397 AGCATAGCACCTGTCATTGTACCCACTGTCAGCGGATTTCTTCTTAGTCAGGACCCTGAG 1456

Qy       361 PheGlyTrpArgAsnValPhePheLeuLeuPheAlaValAsnLeuLeuGlyLeuLeuPhe 380
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1457 TTTGGGTGGAGGAATGTCTTCTTCTTGCTGTTTGCCGTTAACCTGTTAGGACTACTCTTC 1516

Qy       381 TyrLeuIlePheGlyGluAlaAspValGlnGluTrpAlaLysGluArgLysLeuThrArg 400
             ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      1517 TACCTCATATTTGGAGAAGCAGATGTCCAAGAATGGGCTAAAGAGAGAAAACTCACTCGT 1576

Qy       401 Leu 401
             |||
Db      1577 TTA 1579
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APPENDIX B

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RESULT 8
AR036571
LOCUS       AR036571               1780 bp    DNA     linear   PAT 29-SEP-1999
DEFINITION  Sequence 19 from patent US 5872237.
ACCESSION   AR036571
VERSION     AR036571.1  GI:5953239
KEYWORDS    .
SOURCE      Unknown.
  ORGANISM  Unknown.
            Unclassified.
REFERENCE   1  (bases 1 to 1780)
  AUTHORS   Feder,J.Nathan., Kronmal,G.Scott., Lauer,P.M., Ruddy,D.A.,
            Thomas,W., Tsuchihashi,Z. and Wolff,R.K.
  TITLE     Megabase transcript map: novel sequences and antibodies thereto
  JOURNAL   Patent: US 5872237-A 19 16-FEB-1999;
FEATURES             Location/Qualifiers
     source          1. .1780
                     /organism="unknown"
                     /mol_type="unassigned DNA"
ORIGIN

  Query Match             90.7%;  Score 1490.2;  DB 6;  Length 1780;
  Best Local Similarity   99.8%;  Pred. No. 0;
  Matches 1492;  Conservative    0;  Mismatches    3;  Indels    0;  Gaps    0;

Qy        144 GGTGAAAACCATTCACTAGGAGAGGAGAAACACAATGGCCACCAAGACAGAGTTGAGTCC 203
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        286 GGTGAAAACCATTCACTAGGAGAGGAGAAACACAATGGCCACCAAGACAGAGTTGAGTCC 345

Qy        204 CACAGCAAGGGAGAGCAAGAACGCACAAGATATGCAAGTGGATGAGACACTGATCCCCAG 263
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        346 CACAGCAAGGGAGAGCAAGAACGCACAAGATATGCAAGTGGATGAGACACTGATCCCCAG 405

Qy        264 GAAAGTTCCAAGTTTATGTTCTGCTCGCTATGGAATAGCCCTCGTCTTACATTTCTGCAA 323
              ||||| ||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        406 GAAAGGTCCAAGTTTATGTTCTGCTCGCTATGGAATAGCCCTCGTCTTACATTTCTGCAA 465

Qy        324 TTTCACAACGATAGCACAAAATGTCATCATGAACATCACCATGGTAGCCATGGTCAACAG 383
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        466 TTTCACAACGATAGCACAAAATGTCATCATGAACATCACCATGGTAGCCATGGTCAACAG 525

Qy        384 CACAAGCCCTCAATCCCAGCTCAATGATTCCTCTGAGGTGCTGCCTGTTGACTCATTTGG 443
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Db        526 CACAAGCCCTCAATCCCAGCTCAATGATTCCTCTGAGGTGCTGCCTGTTGACTCATTTGG 585

Qy        444 TGGCCTAAGTAAAGCCCCAAAGAGTCTTCCTGCAAAGTCCTCAATACTTGGGGGTCAGTT 503
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Db        586 TGGCCTAAGTAAAGCCCCAAAGAGTCTTCCTGCAAAGTCCTCAATACTTGGGGGTCAGTT 645

Qy        504 TGCAATTTGGGAAAGGTGGGGCCCTCCACAAGAACGAAGCAGACTCTGCAGCATTGCTTT 563
              |||||||||||||| ||||||||||||||||||||||||||||||||||||||||||||
Db        646 TGCAATTTGGGAAAAGTGGGGCCCTCCACAAGAACGAAGCAGACTCTGCAGCATTGCTTT 705

Qy        564 ATCAGGAATGTTACTGGGATGCTTTACTGCCATCCTCATAGGTGGCTTCATTAGTGAAAC 623
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Db        706 ATCAGGAATGTTACTGGGATGCTTTACTGCCATCCTCATAGGTGGCTTCATTAGTGAAAC 765

Qy        624 CCTTGGGTGGCCCTTTGTCTTCTATATCTTTGGAGGTGTTGGCTGTGTCTGCTGCCTTCT 683
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        766 CCTTGGGTGGCCCTTTGTCTTCTATATCTTTGGAGGTGTTGGCTGTGTCTGCTGCCTTCT 825

Qy        684 CTGGTTTGTTGTGATTTATGATGACCCCGTTTCCTATCCATGGATAAGCACCTCAGAAAA 743
              |||||||||||||||||||||||||| ||||||||||||||||||||||||||||||||
Db        826 CTGGTTTGTTGTGATTTATGATGACCCCTTTTCCTATCCATGGATAAGCACCTCAGAAAA 885

Qy        744 AGAATACATCATATCCTCCTTGAAACAACAGGTCGGGTCTTCTAAGCAGCCTCTTCCCAT 803
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Db        886 AGAATACATCATATCCTCCTTGAAACAACAGGTCGGGTCTTCTAAGCAGCCTCTTCCCAT 945

Qy        804 CAAAGCTATGCTCAGATCTCTACCCATTTGGTCCATATGTTTAGGCTGTTTCAGCCATCA 863
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Db        946 CAAAGCTATGCTCAGATCTCTACCCATTTGGTCCATATGTTTAGGCTGTTTCAGCCATCA 1005

Qy        864 ATGGTTAGTTAGCACAATGGTTGTATACATACCAACTTACATCAGCTCTGTGTACCATGT 923
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Qy        924 TAACATCAGAGACAATGGACTTCTATCTGCCCTTCCTTTTATTGTTGCCTGGGTCATAGG 983
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Db       1066 TAACATCAGAGACAATGGACTTCTATCTGCCCTTCCTTTTATTGTTGCCTGGGTCATAGG 1125

Qy        984 CATGGTGGGAGGCTATCTGGCAGATTTCCTTCTAACCAAAAAGTTTAGACTCATCACTGT 1043
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Db       1126 CATGGTGGGAGGCTATCTGGCAGATTTCCTTCTAACCAAAAAGTTTAGACTCATCACTGT 1185

Qy       1044 GAGGAAAATTGCCACAATTTTTAGGAAGTCTCCCCTCTTCAGCACTCATTGTGTCTCTGCC 1103
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Db       1186 GAGGAAAATTGCCACAATTTTTAGGAAGTCTCCCCTCTTCAGCACTCATTGTGTCTCTGCC 1245

Qy       1104 TTACCTCAATTCCGGCTATATCACAGCAACTGCCTTGCTGACGCTCTCTTGCGGATTAAG 1163
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Db       1246 TTACCTCAATTCCGGCTATATCACAGCAACTGCCTTGCTGACGCTCTCTTGCGGATTAAG 1305

Qy       1164 CACATTGTGTCAGTCAGGGATTTATATCAATGTCTTAGATATTGCTCCAAGGTATTCCAG 1223
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Db       1306 CACATTGTGTCAGTCAGGGATTTATATCAATGTCTTAGATATTGCTCCAAGGTATTCCAG 1365

Qy       1224 TTTTCTCATGGGAGCATCAAGAGGATTTTCGAGCATAGCACCTGTCATTGTACCCACTGT 1283
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Db       1366 TTTTCTCATGGGAGCATCAAGAGGATTTTCGAGCATAGCACCTGTCATTGTACCCACTGT 1425

Qy       1284 CAGCGGATTTCTTCTTAGTCAGGACCCTGAGTTTGGGTGGAGGAATGTCTTCTTCTTGCT 1343
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Db       1426 CAGCGGATTTCTTCTTAGTCAGGACCCTGAGTTTGGGTGGAGGAATGTCTTCTTCTTGCT 1485

Qy       1344 GTTTGCCGTTAACCTGTTAGGACTACTCTTCTACCTCATATTTGGAGAAGCAGATGTCCA 1403
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Db       1486 GTTTGCCGTTAACCTGTTAGGACTACTCTTCTACCTCATATTTGGAGAAGCAGATGTCCA 1545

Qy       1404 AGAATGGGCTAAAGAGAGAAAACTCACTCGTTTATGAAGTTATCCCACCTTGGATGGAAA 1463
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1546 AGAATGGGCTAAAGAGAGAAAACTCACTCGTTTATGAAGTTATCCCACCTTGGATGGAAA 1605

Qy       1464 AGTCATTAGGCACCGTATTGCATAAAATAGAAGGCTTCCGTGATGAAAATACCAGTGAAA 1523
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Db       1606 AGTCATTAGGCACCGTATTGCATAAAATAGAAGGCTTCCGTGATGAAAATACCAGTGAAA 1665

Qy       1524 AGATTTTTTTTTCCTGTGGCTCTTTTCAATTATGAGATCAGTTCATTATTTTATTCAGAC 1583
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1666 AGATTTTTTTTTCCTGTGGCTCTTTTCAATTATGAGATCAGTTCATTATTTTATTCAGAC 1725

Qy       1584 TTTTTTTTGAGAGAAATGTAAGATGAATAAAAATTCAAATAAAATGATAACTAAG 1638
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1726 TTTTTTTTGAGAGAAATGTAAGATGAATAAAAATTCAAATAAAATGATAACTAAG 1780
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